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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,976	09/20/2000	Lawrence W. Stanton	SCIOS.014A	8472

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1655	8

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/665,976	Stanton et al
Examiner	**Art Unit**
Jehanne Souaya	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 20, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-29* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1(a-h) and 2-7, drawn to nucleic acid molecules of SEQ ID NO 2, vectors and host cells comprising the nucleic acid, classified in class 536, subclass 23.1 and class 435, subclass 320.1 and 325.

II. Claim 1(i), drawn to an antisense oligonucleotide capable of inhibiting translation of the mRNA encoded by a gene encoding the polypeptide of SEQ ID NO 1, classified in class 536, subclass 23.1.

III. Claims 9-10, drawn to a polypeptides of SEQ ID NO 1, classified in class 530, subclass 350.

IV. Claims 11-12, and 18-19, drawn to a pharmaceutical composition comprising polypeptides of SEQ ID NO 1, pharmaceutical compositions comprising an agonist or antagonist of the polypeptide of SEQ ID NO 1 and a method of treatment of a cardiac, renal or inflammatory disease comprising administering to a patient in need of an effective amount of a polypeptide of SEQ ID NO 1 or an agonist or antagonist thereof, classified in class 514, subclass 2.

V. Claims 13 and 15, drawn to antibodies that bind to the polypeptides of SEQ ID NO 2, classified in class 530, subclass 387.1.

VI. Claims 14 and 17, drawn to an agonist or antagonist of the polypeptide of SEQ ID NO 1, classified in class 514, subclass 1.

VII. Claims 16 and 20, drawn to a pharmaceutical composition comprising an antibody and a method of treating a cardiac, renal, or inflammatory disease comprising administering an effective amount of an antibody therapeutic, classified in class 424, subclass 130.1.

VIII. Claim 8, drawn to a method for producing a polypeptide comprising culturing a nucleic acid under conditions such that the polypeptide is expressed and isolating the polypeptide, classified in class 435, subclass 71.1.

IX. Claims 21-29, drawn to a nucleic acid array, a method of detection using the array and a kit comprising the array, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I -VII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The nucleic acid of group II exists as a single strand and is used to inhibit translation of mRNA. The polypeptide of group III is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The pharmaceutical composition of group IV comprises a polypeptide and a pharmaceutical carrier, which makes the polypeptide appropriate for use as a therapeutic. While the antibody of group V is also composed of amino acids linked by peptide

bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The pharmaceutical composition of group VII comprises an antibody and a pharmaceutical carrier which makes the antibody appropriate for use as a therapeutic. The agonist or antagonist of group VI could be made up of inorganic molecules that modulate the activity or expression of a polypeptide The products of groups I-VII can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antisense molecule of group II can be used to inhibit translation, the antibody of group V can be used in immunoassays, the pharmaceutical composition of group VII can be used in methods of immunotherapy, the polypeptide of group III can be used to make a fusion protein with an enzymatic function, the pharmaceutical composition of group IV can be used in methods of treatment comprising a protein, or an agonist or antagonist of a protein which can be used to enhance or inhibit the activity of a protein. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I-VII are patentably distinct from each other.

The inventions of groups VIII and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used to make probes and primers for detection and amplification purposes.

The inventions of groups VIII and II, IV-VII, & IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of group VIII is not capable of use with any of the products of groups II, IV-VII , IX or the method of group IX. The different inventions have different modes of operation, requiring different reagents and reaction conditions, different functions and different effects.

The inventions of groups VIII and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of group III can be made synthetically.

The inventions of groups IX and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because 1) the utility of a polynucleotide array does not necessarily depend on the utility

of each separate polynucleotide in the array, and 2) the polynucleotide array of Group IX can be used in a method to identify differential expression of many different genes. The subcombination has separate utility such as the distinct polynucleotides of Group I can be used in recombinant methods to express proteins.

The inventions of groups IX and II-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid array and method of detecting nucleic acids of group IX is not capable of use with any of the products of groups II-VII or the method of group VIII. The different inventions have different modes of operation, requiring different reagents and reaction conditions, different functions and different effects.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-IX, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1655
DEC. 14, 2001